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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/150,947	09/10/1998	RAYMOND KAEMPFER	A31967-PCT-U	7084

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/150,947

Applicant(s)

KAEMPFER ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50-99 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 65-75 is/are allowed.
- 6) ☒ Claim(s) 50-64 and 76-99 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 22, 2004 has been entered.

Accordingly claims 50-99 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 88-99 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a new matter rejection is maintained.

Applicants are asserting that the specification notes that all the discussed toxins contain at least the motifs, KK and QELD (specification page 26, lines 6-9). Applicants further assert that it is within the knowledge of one of skill in the art to detect sequences in an alignment of various sequences that exhibit common or substantially identical residues at the same positions, for example, substantially identical residues in terms of polarity, charge and hydrophobicity, such as SEQ ID NO: 13-18. Applicants submit that

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SEQ ID NO: 13-18 are clearly derived from the sequences set forth in SEQ ID NO: 1-11.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that the specification notes that all the discussed toxins contain at least the motifs, KK and QELD (specification page 26, lines 6-9). However, Applicants will appreciate that not a single one of SEQ ID NO: 13-18 require all of these amino acids. Specifically, claim 93, directed to SEQ ID NO: 18, requires only the C-terminal D residue, every other amino acid in the sequence is selected from multiple wild card amino acids. Accordingly, absent a specific statement of such a broad encompassing claim, the attempt to add these sequences (SEQ ID NO: 13-18) after the filing date is considered new matter.

Applicants are reminded that this new matter rejection is relevant to the computer and paper copy of the sequence listing.

2. The rejection of claims 65-75 and 88-99 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is withdrawn in view of Applicants amendments.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The rejection of claims 50-64 and 76-87 under 35 U.S.C. 102(b) as being anticipated by Tice et al is maintained.

This rejection has specifically been withdrawn from claims 65 and 68 in view of Applicants amendments.

Applicants will further note that claims 76-87 have not been amended to recite "consisting of" despite arguments to the contrary. Given that claims 76-87 have not been amended as argued, these claims remain rejected for reasons of record.

Applicants are asserting that the claims have been amended to recite "consisting" of the identified region, and that the antagonist domain is limited to a peptide no longer than the amino acid residues 141-172 of SEB. Applicants further assert that the term "homologous" is well defined in the specification as to the claimed peptides. Finally, Applicants assert that Tice fails to disclose a peptide that is capable of antagonizing toxin-mediated T-lymphocyte activation.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the claims have been amended to recite "consisting" of the identified region, and that the antagonist domain is limited to a peptide no longer than the amino acid residues 141-172 of SEB. However, Applicants are again

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respectfully directed back to their claim language. No recitation of “consisting of” amino acids 141-172 of SEB is found. Consequently, the claim is simply not limited to this length of a peptide. Furthermore, the claims specifically recite that the claimed peptide is “homologous” to the identified consisting of region. Dictionary.com defines “homologous” as “having the same evolutionary origin.” Given that the protein disclosed by Tice et al is not fused to another non-homologous protein, it is deemed to be “consisted of” a homologous protein. Accordingly, each and every limitation of the claims remains anticipated.

Second, Applicants further assert that the term “homologous” is well defined in the specification as to the claimed peptides. However, as set forth above, dictionary.com defines homologous as having the same evolutionary origin. Given that the claimed peptide and the full-length protein from which it was taken, clearly have the same evolutionary origin, the disclosure of Tice et al is deemed to anticipate the claims. Furthermore, Applicants will note that page 26 of the specification refers to “limited homology” being observed between proteins exhibiting less than 50% identity.

Finally, Applicants assert that Tice fails to disclose a peptide that is capable of antagonizing toxin-mediated T-lymphocyte activation. However, the protein disclosed by Tice et al meets each and every structural requirement set forth in the claims. Consequently, the activity of antagonizing toxin mediated T-lymphocyte activation is deemed an inherent property of the disclosed protein, given that it is structurally identical to the peptides claimed.

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Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 89-90, and 92-93 under 35 U.S.C. 102(b) as being anticipated by Ratti et al is withdrawn in view of Applicants amendments.

5. The rejection of claims 88 and 94 under 35 U.S.C. 102(b) as being anticipated by Galinski et al is withdrawn view of Applicants amendments.

6. The rejection of claims 91 and 97 under 35 U.S.C. 102(b) as being anticipated by Spriggs et al is withdrawn in view of Applicants amendment.

7. The amendment filed February 13, 2004 as objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure is withdrawn in view of Applicants amendment.

Claims 65-75 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
March 7, 2005